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Attorney Docket No. 19459P-002200US

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Transmitted herewith for filing under 37 CFR 1.53(b) is the
[X] Re-issue patent application
for U.S. Patent No. 5,879,380

Inventors: Menno Kalmann and Franciscus Laurens Moll

For: ASSEMBLY FOR TREATING BLOOD VESSELS AND A METHOD THEREFOR

Enclosed are:
[X] Copy of Original Letters Patent No. 5,879,380 along with New Claims Nos. 21-54.
[X] An executed Reissue Application Declaration.
[X] Consent of Assignee and Offer to Surrender Original Letters Patent Under 37 C.F.R. §§ 1.172 and 1.178
[X] Certificate Under 37 C.F.R. §§ 3.73(b).
[X] Request for Transfer of Drawings Under 37 C.F.R. § 1.174.
[X] Verified Statement Claiming Small Entity Status
[X] Power of Attorney
[ ]
[ ]

	(Col. 1)	(Col. 2)	SMALL ENTITY			OTHER THAN SMALL ENTITY	
FOR:	NO. FILED	NO. EXTRA	RATE	FEE	OR	RATE	FEE
BASIC FEE				$355.00	OR		$690.00
TOTAL CLAIMS	___	= 34	x $9.00 =	$306.00	OR	x $18.00 =	$
INDEP. CLAIMS	___	= 2	x $39.00 =	$ 80.00	OR	x $78.00 =	$
[ ] MULTIPLE DEPENDENT CLAIM PRESENTED			+ $130.00 =		OR	+ $260.00 =	
* If the difference in Col. 1 is less than 0, enter "0" in Col. 2.			TOTAL	$741.00	OR	TOTAL	$

[ ]
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It is requested that all future correspondence relating to this application for reissue of United States Letters Patent No. 5,879,380 be addressed to:

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Please charge Deposit Account No. 20-1430 as follows:
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[ ] A check for $_____ is enclosed.
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Respectfully submitted,
TOWNSEND and TOWNSEND and CREW LLP

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VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

Applicant or Patentee: Vascular Architects, Inc.
Application or Patent No.: Reissue Patent Application based on U.S. Patent No. 5,879,380
Filed or Issued: Herewith
Title: Assembly for Treating Blood Vessels and a Method Therefor

I hereby declare that I am:

☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Small Business Concern: Vascular Architects, Inc.
Address of Small Business Concern: 1830 Bering Drive, San Jose, CA 95112

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled Assembly for Treating Blood Vessels and Method Therefor by inventor(s) Menno Kalmann and Franciscus Laurens Moll described in:

☒ the specification filed herewith.
☐ Application No. _____, filed _____.
☒ Patent No. 5,879,380, issued March 9, 1999.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

Name _____
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Bruce J. Barclay
Title of Person if Other than Owner: President and Chief Executive Officer, Vascular Architects, Inc.
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SIGNATURE _____ DATE Oct 12, 2000

Attorney Docket No.: 19459-002200US

REISSUE PATENT APPLICATION

ASSEMBLY FOR TREATING BLOOD VESSELS AND A METHOD THEREFOR

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United States Patent [19]
Kalmann et al.

[11] **Patent Number: 5,879,380**
[45] **Date of Patent: Mar. 9, 1999**

[54] **ASSEMBLY FOR TREATING BLOOD VESSELS AND A METHOD THEREFOR**

[75] Inventors: **Menno Kalmann**, Elspeet; **Franciscus Laurens Moll**, La Bosch en Duin, both of Netherlands

[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **809,630**

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§ 102(e) Date: **Jun. 27, 1997**

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PCT Pub. Date: **Apr. 11, 1996**

[30] **Foreign Application Priority Data**

Oct. 4, 1994 [NL] Netherlands 9401633

[51] **Int. Cl.**[6] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 128/898

[58] **Field of Search** 606/194, 195; 623/1

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,665,918 5/1987 Garza et al. .

5,360,443	11/1994	Barone et al.	606/194
5,480,423	1/1996	Ravenscroft et al.	606/194
5,522,881	6/1996	Lentz .	
5,603,721	2/1997	Lau et al.	606/194
5,662,700	9/1997	Lazarus	606/194

FOREIGN PATENT DOCUMENTS

0 119 688	9/1984	European Pat. Off. .
0 274 846	7/1988	European Pat. Off. .
WO 90/01969	3/1990	WIPO .
WO 94/04096	3/1994	WIPO .

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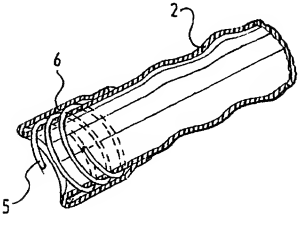
Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

The invention relates to a blood vessel treating assembly including an artificial blood vessel inner layer such as an artificial tunica-intima for replacing a section of blood vessel inner layer previously removed from a blood vessel and/or for covering a predetermined length of a damaged blood vessel inner layer. The artificial blood vessel inner layer is associated with the existing blood vessel in such a way as to substantially stop any loose parts of the blood vessel from obstructing the stream of blood through the blood vessel. A novel method for introducing the the artificial blood vessel inner layer into the blood vessel is also disclosed.

20 Claims, 5 Drawing Sheets



ASSEMBLY FOR TREATING BLOOD VESSELS AND A METHOD THEREFOR

This invention relates to an assembly for the treating of blood vessels and more specifically to an assembly for the replacing of and/or covering up of damaged, blood vessel inner layers and to a method therefor.

An often occurring medical problem is the silting up of blood vessels with for instance calcium, so-called arteriosclerosis. Because of this, a blockage of the blood vessel occurs, so-called stenosis.

Stenosis of blood vessels which leads to a narrowing and, in some cases, complete blocking of the blood vessel can lead to dangerous consequences for the patient. Circulatory problems and a deteriation in health can ensue. Advanced stenosis, if not operated upon, can cause wastage and death of body tissue, necessitating, in certain instances, in amputation.

A known procedure for unblocking blood vessels, 'End artery ectomy', is to separate the inner layer of the blood vessel, the so called tunica-intima, from the blood vessel wall, to cut through and sever the tunica-intima over the blocked length of the bloodvessel and then to remove the tunica-intima plus blockage from the body. A new tunica-intima then grows back to replace this removed tunica-intima.

A problem here is that this new tunica-intima, the so called neo-tunica-intima has the tendency to undergo restenosis, i.e. to silt up again, at a quicker rate than the original tunica-intima.

Another problem is that the original tunica-intima is usually separated from the blood vessel wall upto a distance just past where it is to be severed. Hence on removal of the original tunica-intima, a small piece of this is left hanging loosely in the blood stream, a factor which can cause and hasten the restenosis of the blood vessel.

A blood vessel which is particularly susceptible to stenosis is the artery between the groin and the knee.

It is an object of the present invention to obviate at least one of these problems. To this end there is provided, according to a first aspect of the present invention, a blood vessel treating assembly comprising:

an artificial blood vessel inner layer such as an artificial tunica-intima or the like for replacing a section of blood vessel inner layer previously removed from the blood vessel and/or for covering a predetermined length of damaged blood vessel inner layer, wherein said artificial blood vessel inner layer is associated with the existing blood vessel in such a way as to substantially withhold any loose parts of the blood vessel from obstructing the stream of blood through said blood vessel, and

introducing means for introducing the artificial blood vessel inner layer into the blood vessel.

In this way an artificial new tunica-intima to replace the old tunica-intima over the removed length thereof and which prevents the re-growing of a natural 'neo-tunica-intima', can be introduced into a blood vessel, to just past the piece of loose hanging original tunica-intima left after removal of a section of the original tunica-intima for instance, this artificial new tunica-intima made of such material as to cause a minimum of restenosis of the blood vessel to occur and which pushes the old loose hanging piece of left behind tunica-intima back against the blood vessel wall where it re-grows onto the blood vessel wall and thus no longer flaps about in the blood stream.

According to a second aspect of the present invention there is provided an artificial blood vessel inner layer, such

as an artificial tunica-intima or the like, made of any suitable synthetic material and comprising diameter arranging means for increasing and/or decreasing the diameter of the tube-like section, preferably for use with the above mentioned assembly.

According to a third aspect of the present invention there is provided introducing means for introducing an artificial blood vessel inner layer, such as an artificial tunica-intima or the like, into a blood vessel, preferably for use with the assembly and/or the artificial blood vessel inner layer as mentioned above.

According to a fourth aspect of the present invention there is provided a method of replacing a previously removed inner layer of a blood vessel and/or for covering a predetermined length of damaged blood vessel inner layer comprising the steps of inserting a blood vessel treating assembly as mentioned above, via an incision, upto a predetermined distance into a blood vessel, increasing the diameter of the artificial blood vessel inner layer to push against the blood vessel walls, whereafter the introducing means are removed and joining the end of the artificial blood vessel inner layer to the existing blood vessel near the incision.

According to a fifth aspect of the present invention there is provided a method of increasing and/or decreasing the diameter of a length of artificial blood vessel inner layer, as mentioned above, or the like, comprising bringing a length of memory metal associated with the artificial blood vessel inner layer to its preprogrammed activation temperature whereafter expansion/contraction of the memory metal effectively increases/decreases the diameter of the length of artificial blood vessel inner layer.

According to a further aspect of the present invention there is provided an assembly comprising a tube-like section with at least one length of memory metal associated therewith, pre-programmed to assume a desired form and/or expand and/or contract at a pre-determined activation temperature, and introducing means for introducing the tube-like section into a passage-like area.

Further advantages, characteristics and details of the present invention will become clear from the following description with reference to the accompanying drawings which show:

FIG. 1 a perspective partly cut away view of a preferred embodiment of the assembly according to the present invention, during introduction into the artery between the groin and the knee;

FIG. 2 a partly cut away perspective view of the artificial blood vessel inner layer of the assembly from FIG. 1;

FIGS. 3 to 6 partly cut away perspective views showing the succesive steps of the assembly from FIG. 1 carrying out introduction of the artificial blood vessel inner layer from FIG. 2, into a blood vessel;

FIG. 7 a partly cut away perspective view of an embodiment of the artificial blood vessel inner layer according to the present invention, when in position within a blood vessel.

FIGS. 8 to 9 partly cut away perspective views of a second embodiment of the present invention.

The assembly 1 (FIG. 1) is introduced into the artery between the groin and the knee, for example, preferably via an incision already made for the removal of the original tunica-intima plus blockage.

This yields the advantage that further incisions for introduction of the assembly into the blood vessel need not be made into the patient, which in turn yields the benefits of reduced stress on the patient, reduced operation and recovery time and accordingly low hospital costs.

The assembly 1 comprises an artificial blood vessel inner layer 2 (see FIGS. 2 to 7) and introducing means for introducing the artificial blood vessel inner layer into the blood vessel.

The introducing means preferably comprise a catheter-like element 3 (see FIGS. 1, 3–6) which is preferably operated from outside of the body (see FIG. 1).

The artificial blood vessel inner layer 2 (FIGS. 2–7), which preferably takes the form of a blood vessel tunica-intima, comprises a tube-like section of synthetic material.

A protective cover is preferably associated with the assembly 1, this preferably taking the form of a removeable sheath 4 (FIGS. 3, 4) which extends from the front of the assembly 1 to the catheter operator.

This protective sheath 4 ensures that minimal damage is incurred to the blood vessel wall during introduction of the assembly 1 and that the artificial tunica-intima 2 is substantially protected from any possible interferences which could hinder introduction.

Diameter arranging means are preferably associated with the tube-like section of synthetic material, said diameter arranging means preferably being a length of preprogrammed memory metal 5 (FIGS. 2–7). These diameter arranging means are often referred to as a "stent".

The tube-like section of the artificial tunica-intima 2 is preferably folded over at its leading end (see FIGS. 2–6), the resulting fold 6 of for example 2 cm preferably enclosing the length of memory metal 5 which preferably takes the form of a coil.

The artificial tunica-intima 2 is preferably made of a fluoro carbon polymer, by choice the polymer which goes under the name of teflon, a trademarked name, of Du Pont. Clinical tests have shown that teflon is efficient in ensuring a minimum restenosis of blood vessels.

The fact that the coil of memory metal 5 is enclosed as it were in the fold 6 of the artificial tunica-intima 2, means that the memory metal 5 does not come into direct contact with either the blood vessel or the blood stream, so that calcium or any other such blood vessel blocking material is not given a 'foot-hold', on the memory metal, on which it could remain, a factor which further reduces restenosis and/or the rate at which restenosis occurs.

For example, the coil of memory metal can be preprogrammed to increase from a diameter of about 2 mm at room temperature to a diameter of about 8 mm at a temperature of about 35° C. in the blood vessel.

The fact that the length of memory metal is preferably in the form of a coil, ensures that a uniform expansion/contraction of the artificial tunica-intima occurs when the preprogrammed temperature of the memory metal is reached.

In use the assembly is inserted into the blood vessel via an incision already made (see FIG. 1). A guiding wire (not shown) can be introduced into the blood vessel, before introduction of the assembly 1, whereafter the assembly 1 can be pushed over this guiding wire and through the blood vessel.

Blood vessel widening means, for widening the blood vessel during introduction of the assembly, bunging means for blocking off the passage of blood into the assembly during introduction of the assembly into the blood vessel, which could cause introduction complications, and pressure exerting means for pushing the introduced artificial tunica-intima against the blood vessel walls when in position, are preferably associated with the assembly, and preferably take the form of a cone-like element 7 mounted on the front of the catheter-like element 3 (see FIGS. 3–6).

The cone-shape of the cone-like element **7** enables the assembly **1** to easily follow the passage of the blood vessel, pushing the blood vessel walls apart as it goes in order to facilitate introduction of the assembly **1**.

During introduction of the assembly **1**, the cone-like element **7** is pushed to a point just past were the old tunica-intima was severed so that the fold **6** of the artificial tunica-intima **2** is encircled by the loose hanging remaining piece of the original tunica-intima **8** (see FIGS. 3–7). At this point forward movement of the assembly **1** is stopped.

The protective sheath **4** is then pulled back off the assembly **1** whilst the assembly **1** itself is held in position (FIG. **4**). The artificial tunica-intima **2**, still in its small diameter state, at this point in time, is relatively tightly wrapped around the catheter-like element **3** (see FIG. **4**).

During withdraw of the protective sheath **4**, it was found during clinical tests that the artificial tunica-intima **2** sometimes had the inclination to be pulled back along the catheter-like element **3** together with the sheath **4**. In order to prevent this, the catheter-like element **3** can be locally given a somewhat smaller diameter **9** at the position where the memory metal coil **5** is associated with the fold **6** (see FIGS. 3–6), so that the fold **6** and coil of memory metal **5** remain secured in the desired position on withdrawal of the protective sheath **4**.

A further feature of the protective sheath is that it aids in insulating the coil of memory metal from the temperature in the blood vessel during introduction of the assembly, so that the coil does not assume its preprogrammed shape until reaching its activation temperature which occurs when the sheath is withdrawn. This prevents the coil from expanding at an undesired position within the blood vessel.

A short period after withdrawal of the protective sheath the coil of memory metal **5** reaches its activation temperature, whereupon the coil of memory metal **5** increases in diameter and so doing pushes the artificial tunica-intima **2** against the walls of the blood vessel (see FIG. **5**).

The artificial tunica-intima **2** pushes the loose hanging piece of remaining old tunica-intima **8** into the blood vessel wall so that this no longer flaps around in the blood stream (see FIGS. **5–7**).

The diameter of the artificial tunica-intima **2** is now large enough for the catheter-like element **3**, plus the cone-like element **7** to be withdrawn out of the blood vessel, the cone-like element **7** further exerting a certain pressure on the artificial tunica-intima **2** during this withdrawal to further open out and push the latter somewhat into the blood vessel wall (see FIG. **6**).

According to the present invention, it is not necessary to support the artificial tunica-intima over its whole length, whereby unnecessary added pressure is exerted against the blood vessel wall. The artificial tunica-intima, once in place, is held in position by the blood pressure.

After removal of the sheath **4** and the catheter-like element **3**, the artificial tunica-intima **2** can be joined to the blood vessel wall near the incision, preferably by means of stitches. However as shown in FIG. **7** another possibility to secure the artificial tunica-intima in position within the blood vessel is to equip the artificial tunica-intima with a further coil of memory metal so that the both ends of the artificial section of tunica-intima are forced against blood vessel wall.

After a period of time the artificial tunica-intima grows onto the original blood vessel wall.

It will be obvious that during sterilisation, before introduction of the assembly, the memory metal coil should be

temporarily held in its small diameter state, by means of for instance a collar, so that it does not assume its preprogrammed expanded form at this stage.

A further embodiment of the present invention is shown in FIGS. **8** and **9**.

In this embodiment **20**, the length of preprogrammed memory metal, is replaced by a section of gauze-like material **21** (FIGS. **8** and **9**), enclosed within an end section **22** of the artificial tunica-intima.

The end section **22** and artificial intima-tunica are pushed over an expandible balloon **23** and a protective sheath, not shown, is brought thereover. Following introduction, the sheath is removed and the balloon **23** expanded to force the end section **22** against the wall of the blood vessel, whereby it is held in position by the stent **21**, to affix with the blood vessel wall. Blood pressure forces the length of unsupported artificial intima-tunica to affix with the blood vessel wall as in the first embodiment. Following positioning, the balloon **23** is removed.

This stent **21** is preferably made from stainless steel.

The artificial tunica-intima is required to be supple, and have elastic and anti-thrombogenic qualities and is preferably porous, in order to mimic the qualities of the tunica-intima. A suitable matcrial herefor is polytetrafluorethylene made by Dacron.

The material for the artificial tunica-intima can be supplied with endothelial cells in order to further enhance its working as a tunica-intima.

Although the present invention refers to the introduction and placing of an artificial intima tunica, intima tunicas from the patient self and from donors may be introduced and arranged in position according to the present invention.

The present invention thus yields a simple yet efficient introduction of a new artificial inner blood vessel layer, which can be carried out in a short time and with a minimum of discomfort to the patient.

The present invention is not limited to the hereabove described and illustrated embodiments, rather within the range of the following claims, a large number of modifications and variations are conceivable.

We claim:

1. A method for replacing a section of blood vessel inner layer comprising the steps of:

forming an incision into the blood vessel;

removing a section of an inner layer of a blood vessel through the incision, wherein the removal creates at least one end flap in a remaining blood vessel inner layer;

providing an artificial blood vessel inner layer comprising a supple tubular section having inner and outer surfaces, at least one end section of said tubular section folded back over said outer surface creating an enclosure, and a stent enclosed within said enclosure;

inserting the stented end of said artificial inner layer into said blood vessel through the incision in the direction of blood flow;

positioning said artificial inner layer within said blood vessel so that said end section enclosing said stent is positioned adjacent said end at a downstream location from said incision flap; and

retaining said end flap between said end section and said blood vessel by expanding said stent.

2. A method as in claim 1, wherein said providing step comprises providing an artificial blood vessel inner layer having a tubular section comprising a fluoro carbon polymer.

3. A method as in claim 1, wherein said providing step comprises providing an artificial blood vessel inner layer having a tubular section that has a length at least as long as said removed section of blood vessel inner layer.

4. A method as in claim 1, wherein said providing step comprises providing an artificial blood vessel inner layer having a stent comprising a stainless steel gauze.

5. A method as in claim 1, wherein said providing step comprises providing an artificial blood vessel inner layer having a stent comprising a length of memory metal preprogrammed to expand at a determined temperature.

6. A method as in claim 1, wherein said providing step comprises providing an artificial inner layer having an enclosure comprising a fluid-tight enclosure.

7. A method as in claim 1, wherein said positioning step comprises positioning said artificial inner layer using a catheter.

8. A method as in claim 7, wherein said catheter comprises a guide wire and a sheath.

9. A method as in claim 7, wherein said catheter comprises a blood vessel widener.

10. A method as in claim 9, wherein said widener comprises a cone-shaped element operably attached to a distal end of said catheter.

11. A method as in claim 9, wherein said widener comprises an inflatable balloon operably attached to a distal end of said catheter.

12. A method as in claim 9, wherein said widener is wider than said end section during said inserting step and narrower than said end section after said retaining step due to said stent enclosed within said end section expanding during said expanding step.

13. A method as in claim 9, wherein said widener has substantially the same diameter as an internal diameter of said blood vessel.

14. A method as in claim 9, wherein said retaining step comprises using said widener to widen said stent in order to press said end section against said end flap.

15. A method as in claim 1, wherein said retaining step comprises retaining said end flap by expanding said stent so that an outer diameter of said tubular section is approximately equal to an inner diameter of said blood vessel.

16. A method as in claim 1, wherein the providing step comprises providing an artificial blood vessel inner layer further comprising two end sections creating two enclosures and two stents enclosed within said enclosures.

17. A method as in claim 1, further comprising the step of stitching one end section to said blood vessel.

18. A method as in claim 9, further comprising the step of bunging the blood vessel.

19. A method as in claim 18 wherein said bunging step comprises bunging said blood vessel using said widener.

20. A method as in claim 9, further comprising the step of exerting pressure outwardly on said stent with said widener during a withdrawal of said catheter from said blood vessel.

* * * * *

21. A method for replacing a section of blood vessel inner layer comprising the steps of:

forming an incision into the blood vessel;

removing a section of an inner layer of the blood vessel through the incision, wherein the removal creates at least one end flap in a remaining blood vessel inner layer;

providing an artificial blood vessel inner layer comprising a diameter arranging element at one end thereof, creating an expandable end, and a supple tubular section having inner and outer surfaces;

inserting the expandable end of said artificial inner layer into said blood vessel through the incision in the direction of blood flow; and

positioning said artificial inner layer within said blood vessel so that said expandable end is positioned adjacent said remaining blood vessel inner layer at a downstream location from said incision; and

retaining said expandable end against said blood vessel by said diameter arranging element.

22. A method as in claim 21, wherein said providing step comprises providing an artificial blood vessel inner layer having a tubular section comprising a fluoro carbon polymer.

23. A method as in claim 21, wherein said providing step comprises providing an artificial blood vessel inner layer having a tubular section that has a length at least as long as said removed section of blood vessel inner layer.

24. A method as in claim 21, wherein said providing step comprises providing an artificial blood vessel inner layer having a diameter arranging element comprising stainless steel.

25. A method as in claim 21, wherein said providing step comprises providing an artificial blood vessel inner layer having a diameter arranging element comprising a length of memory metal preprogrammed to expand at a determined temperature.

26. A method as in claim 21, wherein said providing step comprises providing an artificial inner layer having an enclosure comprising a fluid-tight enclosure.

27. A method as in claim 21, wherein said providing step is carried out with said diameter arranging element made of a metal.

28. A method as in claim 21, wherein said providing step is carried out with said diameter arranging element in the form of a coil.

29. A method as in claim 21, wherein said providing step is carried out with said diameter arranging element and said supple tubular section made of different materials.

30. A method as in claim 21, wherein said providing step is carried out with said expandable end created by folding a portion of said tubular section back over the outer surface creating an enclosure with said diameter arranging element at least partially captured therein.

31. A method as in claim 21, wherein said providing step is carried out with said expandable end created by at least partially capturing said diameter arranging element within said tubular section.

32. A method as in claim 21, wherein said positioning step comprises positioning said artificial inner layer using a catheter.

33. A method as in claim 32, wherein said catheter comprises an elongate member slidably housed within a hollow sheath.

34. A method as in claim 32, wherein said catheter comprises a blood vessel widener.

35. A method as in claim 34, wherein said widener comprises a cone-shaped element operably attached to a distal end of said catheter.

36. A method as in claim 34, wherein said widener comprises an inflatable balloon operably attached to a distal end of said catheter.

37. A method as in claim 34, wherein said widener is wider than said end section during said inserting step and narrower than said end section after said retaining step due to said diameter arranging element expanding during said expanding step.

38. A method as in claim 34, wherein said widener has substantially the same diameter as an internal diameter of said blood vessel.

39. A method as in claim 34, wherein said retaining step comprises using said widener to widen said diameter arranging element in order to press said end section against said blood vessel.

40. A method as in claim 21, wherein said retaining step comprises expanding said diameter arranging element so that an outer diameter of said tubular section is approximately equal to an inner diameter of said blood vessel.

41. A method as in claim 21, wherein the providing step comprises providing an artificial blood vessel inner layer further comprising a diameter arranging element at each end thereof creating two expandable ends.

42. A method as in claim 21, further comprising the step of stitching one end section to said blood vessel.

43. A method as in claim 34, further comprising the step of bunging the blood vessel.

44. A method as in claim 43 wherein said bunging step comprises bunging said blood vessel using said widener.

45. A method as in claim 34, further comprising the step of exerting pressure outwardly on said diameter arranging element with said widener during a withdrawal of said catheter from said blood vessel.

46. A method for lining a section of a blood vessel comprising the steps of:

forming an incision into the blood vessel;

removing matter from a length of the blood vessel through the incision;

providing an artificial blood vessel inner layer comprising first and second ends, a diameter arranging element at said first end thereof creating a first expandable end, and a supple tubular section having inner and outer surfaces between the first and second ends;

inserting the first expandable end of said artificial inner layer into said blood vessel through the incision;

positioning said artificial inner layer within said blood vessel so that said artificial inner layer covers at least a portion of said length of the blood vessel; and

retaining said artificial inner layer against the blood vessel by expanding said diameter arranging element.

47. A method as in claim 46, wherein said providing step comprises providing an artificial blood vessel inner layer having a tubular section that has a length at least as long as said removed section of blood vessel inner layer.

48. A method as in claim 46, wherein said providing step comprises providing an artificial inner layer having an enclosure comprising a fluid-tight enclosure.

49. A method as in claim 46, wherein said providing step is carried out with said diameter arranging element and said supple tubular section made of different materials.

50. A method as in claim 46, wherein said providing step is carried out with said diameter arranging element and said supple tubular section made of different materials.

51. A method as in claim 46, wherein said positioning step comprises positioning said artificial inner layer using a catheter.

52. A method as in claim 51, wherein said catheter comprises an elongate member slidably housed within a sheath.

53. A method as in claim 51, wherein said catheter comprises a blood vessel widener.

54. A method as in claim 46, wherein said retaining step comprises expanding said diameter arranging element so that an outer diameter of said tubular section is approximately equal to an inner diameter of said blood vessel.

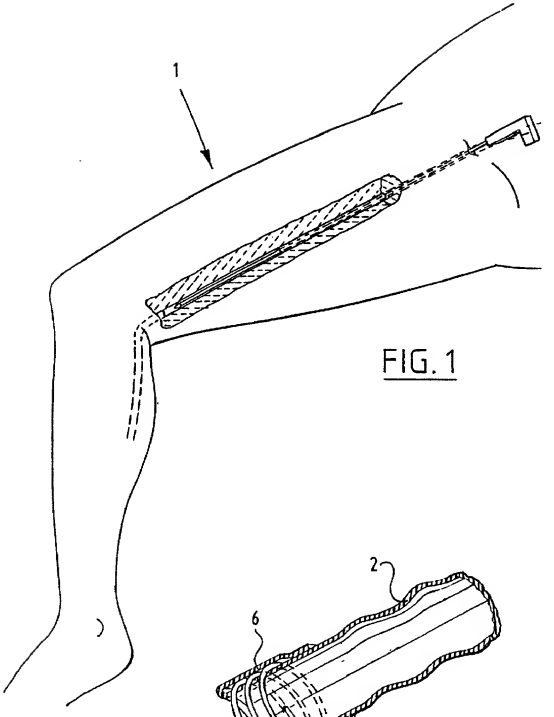


FIG. 1

FIG. 2

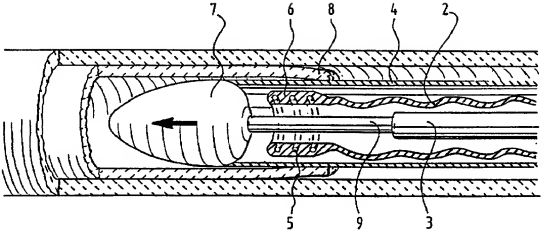


FIG. 3

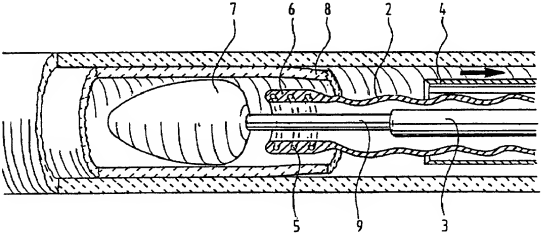


FIG. 4

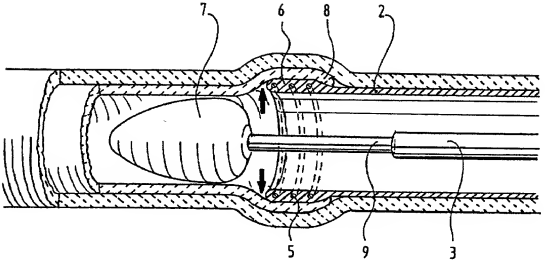


FIG. 5

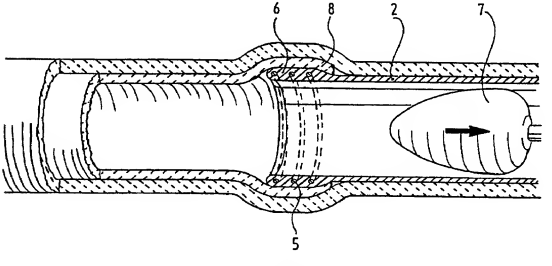


FIG. 6

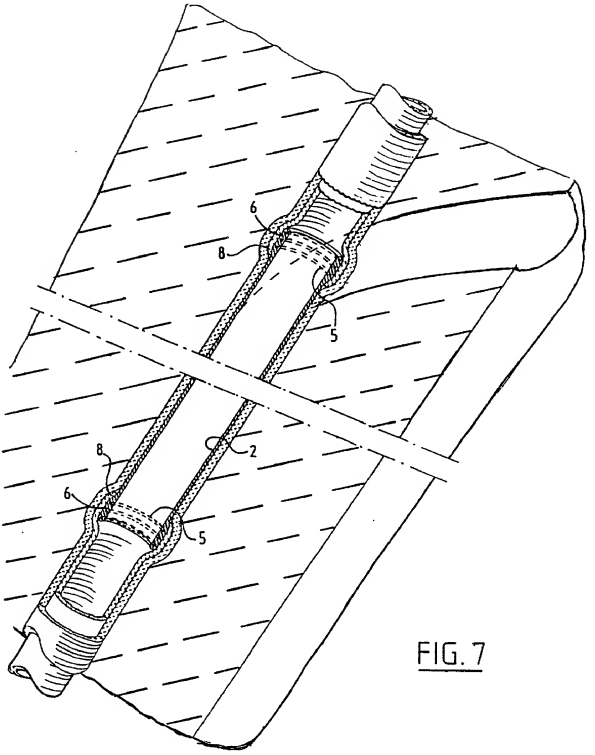


FIG. 7

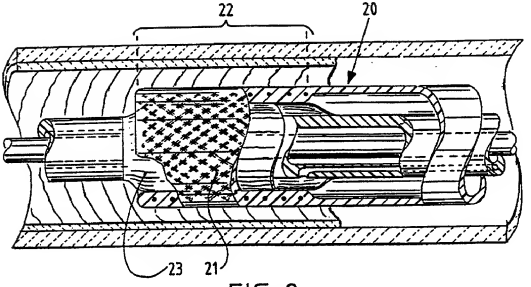


FIG. 8

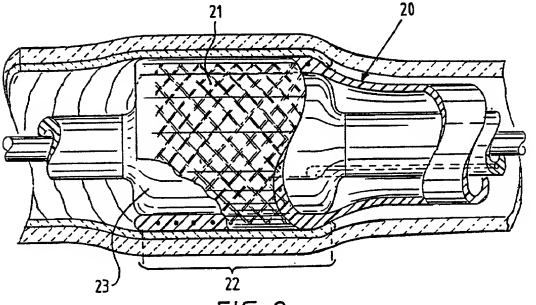


FIG. 9

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On October 18, 2000

TOWNSEND and TOWNSEND and CREW LLP

By: Ron Anton

PATENT
Attorney Docket No.: 19459P-002200US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:

Menno Kalmann et al.

Patent No.: 5,879,380

Issued: March 9, 1999

Application No.: PCT/NL95/00336

Filed: October 4, 1995

For: Assembly for Treating Blood Vessels and a Method Therefor

Examiner: Unassigned

Art Unit: Unassigned

REQUEST FOR TRANSFER OF DRAWINGS under 37 C.F.R. §1.174

Assistant Commissioner for Patents
Box Reissue
Washington, D.C. 20231

Sir:

Applicant formally requests transfer of drawings from the original patent file to the present reissue application.

Respectfully submitted,

James F. Hann
Reg. No. 29,719

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PA 3092336 v1

Attorney Docket No. 19459P-002200US

POWER OF ATTORNEY BY ASSIGNEE

Vascular Architects, Inc. is the Assignee of the invention entitled: Assembly for Treating Blood Vessels and a Method Therefor, the specification of which _____ is attached hereto or _X_ was filed on June 27, 1997 as Application Serial No. 08/809,630, which issued as Patent Number 5,879,380 on March 9, 1999, for which a **Reissue Patent Application** is attached hereto.

Assignee hereby appoints the following attorney(s) and/or agent(s) to prosecute this Reissue Patent Application and transact all business in the Patent and Trademark Office connected therewith.

James F. Hann, Reg. No. 29,719
J. Georg Seka, Reg. No. 24,491
Mark D. Barrish, Reg. No. 36,443

Send Correspondence to:	Direct Telephone Calls to:
James F. Hann TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, CA 94111-3834	James F. Hann Reg. No.: 29,719 (415) 576-0200

Vascular Architects, Inc.

Date: Oct. 12, 2000 By: _____ (Signature)

Name: Bruce J. Barclay
Title: **President and Chief Executive Officer**

PA 3094301 v1

REISSUE APPLICATION DECLARATION BY THE INVENTORS

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first and joint inventor of the subject matter which is claimed in U.S. Patent No. 5,879,380 entitled: **ASSEMBLY FOR TREATING BLOOD VESSELS AND A METHOD THEREFOR**, the specification for which was filed on October 4, 1995 as PCT Int'l Application No. PCT/NL95/00336, and then entered the National Phase as U.S. Patent Application No. 08/809,630 and is attached hereto.

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one other country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119			
COUNTRY (if PCT indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day/month/year)	PRIORITY CLAIMED UNDER 35 USC 119
Netherlands	9401633	04 October 1994	X yes ___ no

I verily believe the original U.S. Pat. No. 5,879,380 is partially inoperative or partially invalid by reason of having claimed less than I had a right to claim in the patent. At least one error in the original patent, which is corrected in the present reissue application, is the limitation of claim 1 which recites that at least one end section of the tubular section is folded back over the outer surface creating an enclosure; this limitation has been removed in claim 21.

All errors corrected in the present reissue application arose without deceptive intent on my part as applicant.

Full Name of Inventor 1:	Last Name: **Kalmann**	First Name: **Menno**	Middle Name or Initial:	
Residence & Citizenship:	City: **Elspeet**	State/Foreign Country: **Netherlands**	Country of Citizenship: **NL**	
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Full Name of Inventor 2:	Last Name: **Moll**	First Name: **Franciscus**	Middle Name or Initial: **Laurens**	
Residence & Citizenship:	City: **La Bosch en Duin**	State/Foreign Country: **Netherlands**	Country of Citizenship: **NL**	
Post Office Address:	Post Office Address: **Duinweg 21,**	City: **La Bosch en Duin**	State/Country: **Netherlands**	Postal Code:

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2
Menno Kalmann	Franciscus Laurens Moll
Date 22/09/2000	Date 22/09/2000

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On October 18, 2000

TOWNSEND and TOWNSEND and CREW LLP

By: Ron Anton

PATENT
Attorney Docket No.: 19459P-002200US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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For: Assembly for Treating Blood Vessels and a Method Therefor

Examiner: Unassigned

Art Unit: Unassigned

CONSENT OF ASSIGNEE AND OFFER TO SURRENDER ORIGINAL LETTERS PATENT under 37 C.F.R. §1.172 and 1.178

Assistant Commissioner for Patents
Box Reissue
Washington, D.C. 20231

Sir:

Vascular Architects, Inc., being owner of all right, title, and interest in U.S. Letters Patent No. 5,879,380 by virtue of a first Assignment recorded Reel 8582, Frame 0922; a second Assignment recorded at Reel 9699, Frame 0922; a first change of name recorded at Reel 010776, Frame 0849; and a second change of name recorded at Reel 010841, Frame 0123, hereby:

1) consents to the filing of the present Reissue Application for the reissue of U.S. Patent No. 5,879,380; and

2) offers to surrender the original of U.S. Letters Patent No. 5,879,380 conditional upon the Reissue of said Letters Patent.

By: _____
Bruce J. Barclay
President and Chief Executive Officer
Vascular Architects, Inc.

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JFH:nsc

PA 3092359 v1

Attorney Docket No. 19459P-002200US

CERTIFICATE UNDER 37 C.F.R. § 3.73(b)

Applicant: Menno Kalmann et al.

Patent No.: 5,879,380 Issued: March 9, 1999

For: Assembly for Treating Blood Vessels and a Method Therefor

Vascular Architects, Inc. , a corporation
(Name of Assignee) (Type of Assignee, e g , corporation, partnership, university, government agency, etc)

certifies that it is assignee of the patent application identified above by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel ____, Frame(s) ____, or for which a copy thereof is attached.

OR

B. ☒ A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: Menno Kalmann and Franciscus Laurens Moll To: Medtronic, Inc.
The document was recorded in the Patent and Trademark Office at
Reel 8582, Frame 0922, or for which a copy thereof is attached.

2. From: Medtronic, Inc. To: Aspect Medical, Inc.
The document was recorded in the Patent and Trademark Office at
Reel 9699, Frame 0922, or for which a copy thereof is attached.

3. From: Aspect Medical, Inc. To: Avatar Incorporated Vascular Architects
The document was recorded in the Patent and Trademark Office at
Reel 010776, Frame 0849, or for which a copy thereof is attached.

4. From: Avatar Incorporated Vascular Architects To: Vascular Architects, Inc.
The document was recorded in the Patent and Trademark Office at
Reel 010841, Frame 0123, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Oct. 12, 2000

Name: Bruce J. Barclay

Title: President and Chief Executive Officer

Signature: Bruce J Barclay